**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF OHIO**
**EASTERN DIVISION**

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| IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION<br><br>This document relates to:<br>*County of Monroe, Michigan v. Purdue Pharma L.P. et al.*,<br>Case No. 1:18-op-45158 | MDL No. 2804<br><br>Case No. 17-md-2804<br><br>Hon. Dan Aaron Polster |

**REPLY IN SUPPORT OF THE MANUFACTURER DEFENDANTS' JOINT MOTION TO DISMISS PLAINTIFF'S SECOND AMENDED COMPLAINT**

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## INTRODUCTION

Plaintiff's Opposition advances superficial arguments and conclusory accusations, while ignoring the dispositive *legal* authorities that compel dismissal here. Indeed, the Opposition begins by focusing entirely on allegations regarding the "severity of the epidemic" in Monroe County. Opp. 1.[1] But no matter how severe the public health crisis, the legitimacy of legal theories cannot be determined on a sliding scale, whereby the graver the facts alleged, the less the law matters.

In particular, Plaintiff strives to avoid MPLA immunity by insisting that it cannot possibly be as broad as the Manufacturer Defendants describe. It is—as the statute itself makes clear and the Michigan Supreme Court has confirmed. In an effort to avoid that result, Plaintiff suggests its claims either are not subject to the statute at all or fit within a narrow exception. But courts have already rejected these arguments, and this Court should do the same. The Michigan Legislature decided to provide pharmaceutical manufacturers with immunity from all claims related to the marketing and selling of medications whenever—as here—the relevant medication was approved by FDA and labelled in conformance with that FDA approval. That decision is dispositive.

Plaintiff's other arguments largely fail for the same reasons as set forth in the *Summit County* briefing and will not be repeated here.[2] Only arguments specific to this case are ad-

[1] Unless otherwise noted, all capitalized terms and acronyms are defined in the Memorandum in Support of the Manufacturer Defendants' Joint Motion to Dismiss Plaintiff's Second Amended Complaint (Dkt. #595-1) ("Motion" or "JM"), emphasis in quotations is added, and internal citations, quotation marks, and alterations are omitted. "Opposition" or "Opp." refers to Plaintiff's Omnibus Memorandum in Opposition (Dkt. #729). Further, because Plaintiff's responses mirror those in *Summit*, the Manufacturer Defendants expressly incorporate by reference their reply brief in the *Summit* action, Dkt. #746 ("*Summit* Reply").

[2] This is the case for the following arguments: defects in Plaintiff's RICO claims, Counts 1 and 2 (*Summit* JM 9-34); preemption of Plaintiff's state law claims, Counts 3-8 (*Summit* JM 34-38; *Summit* Reply 11-13); failure to plead a civil conspiracy, Count 8 (*Summit* JM 51-53; *Summit* Reply 31-32); and statute of limitations as to all claims (*Summit* JM 53-57; *Summit* Reply 36-38).

dressed below, though the outcome is the same: all of Plaintiff's claims fail and the Court should dismiss the 2AC in its entirety.

## ARGUMENT

### I. THE MPLA BARS PLAINTIFF'S STATE LAW CLAIMS.

"[T]he [Michigan] Legislature has determined that a drug manufacturer or seller that has properly obtained FDA approval of a drug product has acted sufficiently prudently so that *no tort liability may lie*." *Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 131 (Mich. 2003). Contrary to Plaintiff's arguments, Opp. 11, MPLA immunity is as total and unyielding as it sounds. Courts have already rejected Plaintiff's policy-based arguments regarding this very statute. *Garcia v. Wyeth-Ayerst Labs.*, 265 F. Supp. 2d 825, 834 (E.D. Mich. 2003), *aff'd*, 385 F.3d 961 (6th Cir. 2004) (rejecting argument that "the immunity [the MPLA] grants to drug manufacturers is too broad"); *see also Cotton v. Johnson & Johnso*n, 2016 WL 9776137, at *3 (E.D. Mich. Dec. 1, 2016) (same). This Court should do the same.

**Plaintiff does not dispute that MPLA immunity generally applies to unlawful marketing claims like those alleged here.** Instead, Plaintiff tries to invoke an *exception* to MPLA immunity that applies only in the narrow circumstance when there has been a federal determination that a pharmaceutical manufacturer defrauded FDA in obtaining approval for its medication. *See* MCL § 600.2946(5)(a); *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004). There are no such allegations in the 2AC. In fact, Plaintiff has expressly *disclaimed* "any allegation of fraud on the FDA." *Summit* Opp. 118-119; Opp. 6. That concession is dispositive.

Plaintiff's insistence that discovery will likely uncover "misrepresentations and omissions made directly to the FDA" and that "[t]he import of such deception . . . is a question of fact for the jury" gets things backwards. Opp. 13, 14. "[A] plaintiff may not establish the exceptions through proof of fraud or bribery, but instead must show that *the FDA has made its own determi-*

*nations* of fraud or bribery." *Ammend v. BioPort, Inc.*, 2006 WL 1050509, at *3 (W.D. Mich. Apr. 19, 2006). Indeed, asking the Court or a jury to make a determination of fraud would run afoul of the Supreme Court's pronouncement that federal law preempts any tort remedies requiring proof of fraud against FDA. *See Garcia*, 385 F.3d at 966. Moreover, the MPLA's exception applies only if there has been a federal finding that defendants intentionally withheld or misrepresented information "*to the [FDA]*." MCL § 600.2946(5)(a); *see also Garcia*, 385 F.3d at 966. Plaintiff, however, alleges misrepresentations in marketing *to physicians*, not FDA, and does not allege any federal findings at all. *See* Opp. 13.

Finally, Plaintiff suggests that immunity does not apply to allegations regarding "*non-branded* promotional efforts," on the ground that they "[were] completely unregulated," *id.* at 14, but then cites two out-of-circuit cases regarding allegations of "*off-label* promotion." That confuses two issues ("non-branded" and "off-label" promotion) and gets them both wrong. First, MPLA immunity applies when the *drugs* at issue were approved by FDA, and does not depend on whether a manufacturer's post-approval promotional activity—branded or non-branded—is FDA-regulated. *See Taylor*, 658 N.W.2d at 131. Second, Michigan "courts have repeatedly rejected" the contention that immunity applies only if drugs are marketed on-label. *Short v. Janssen Pharm., Inc.*, 2015 WL 2201713, at *6 (W.D. Mich. May 11, 2015); *see Cotton*, 2016 WL 9776137, at *2; *White v. SmithKline Beecham Corp.*, 538 F. Supp. 2d 1023, 1030 (W.D. Mich. 2008).

**MPLA immunity applies equally to Plaintiff's diversion claims.** Plaintiff argues that alleged failures to "identify, report, and halt suspicious orders" are not subject to immunity because they do not amount to a "product liability action." Opp. 11. But the MPLA defines "product liability action" broadly to encompass all claims for injuries "*caused by or resulting from* the

production of a product." MCL § 600.2945(h). The term "production," in turn, encompasses "a myriad of activities," *White*, 538 F. Supp. 2d at 1030, including "selling." MCL § 600.2945(i). The 2AC expressly asserts that Plaintiff's diversion claims are brought for injuries purportedly caused by the "*selling* [of] opioids without maintaining effective controls against the diversion of opioids." 2AC ¶ 866. The Court need not look to "creative arguments," Opp. 12, as Plaintiff suggests; it can rely on Plaintiff's own allegations, *see* 2AC ¶¶ 774 (alleging defendants carried out goal of "*selling* prescription opioids without reporting suspicious orders"); 866(a) (accusing defendants of "*selling* opioids in ways that facilitated . . . their flow into the illegal" market).

**Plaintiff's remaining arguments against immunity are baseless.** First, Plaintiff's reliance on *Miller v. Mylan Inc.*, 741 F.3d 674 (6th Cir. 2014), is a red herring. That case explained that MPLA immunity applies to "drugs" but not "combination products." *Id.* Accordingly, Plaintiff now suggests—for the first time—that the Manufacturer Defendants' opioid drugs are actually "best categorized as 'combination products.'" Opp. 14. By contrast, the 2AC expressly states that Plaintiff brings its claims against "manufacturers of prescription opioid *drugs*" for seeking to "expand the market for such *drugs*" while failing to properly "monitor and restrict the . . . distribution of those *drugs*." 2AC ¶ 1. Moreover, the presence of a "combination product" had particular relevance in *Miller* because the plaintiff "carefully crafted her complaint to make clear that" she challenged the purportedly defective "*manner in which*" a fentanyl patch delivered fentanyl. *Miller*, 741 F.3d at 678 (Gibbons, J., concurring). Here, by contrast, Plaintiff challenges the Manufacturer Defendants' marketing and sales practices, *see* 2AC ¶ 1, not the nature of any medicine's delivery mechanism.[3]

[3] The vast majority of drugs at issue here are pills, which are not characterized as "combination products" by FDA or in any caselaw. Nor do the Manufacturer Defendants' prescription opioid products qualify as "combination products" simply because they include "delivery mechanisms" such as "patches, lollipops, and oral delivery systems with extended-release mechanisms." Opp. 14. As relevant here, "combination

Last, Plaintiff's suggestion that immunity does not apply to allegations of "reasonably foreseeable misuse" is flat wrong. Opp. 15. None of Plaintiff's purported authorities on this point even *mentions* the immunity provision. Plaintiff merely observes the general rule that manufacturers are not liable for harm caused by the misuse of a product unless the misuse was reasonably foreseeable. *Id.* This unremarkable proposition has nothing to do with whether MPLA immunity applies.

## II. PLAINTIFF LACKS STANDING.

Even setting aside MPLA immunity, *all* of Plaintiff's claims should be dismissed for lack of standing. The Michigan Supreme Court has made clear that, because a "county is ultimately subordinate to the state," "the authority of counties to sue in matters of local interest cannot be used to undermine the authority of the state to sue in matters of state interest." *In re Certified Question from U.S. Dist. Ct. for E. Dist. of Mich.*, 638 N.W.2d 409, 414 (Mich. 2002). Accordingly, although a matter of statewide concern—like the alleged opioid crisis in this case—may in some cases be of local interest, counties cannot interfere with, and are subordinate to, the position of the State, which has actively exercised its superior authority through an investigation into precisely the alleged conduct at issue here. JM 5.[4]

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products" must include "two or more regulated components, i.e., *drug/device*," 21 C.F.R. § 3.2(e)(1), and "device" specifically excludes products, such as patches, lollipops, and extended-release mechanisms that "achieve [their] primary intended purposes through chemical action" and that are "dependent upon being metabolized for the achievement of [their] primary intended purposes," 21 U.S.C. § 321(h)(3).

[4] Moreover, Plaintiff incorrectly argues that *Associated Builders & Contractors v. City of Lansing*, 880 N.W.2d 765 (Mich. 2016), overruled the statewide concern doctrine. Not so. Although the Court held that matters of state interest also may be of municipal concern, it did not hold that counties may always act concurrently with the State government on matters of statewide concern. *See id.* at 770-72; *see also Deruiter v. Twp. of Byron*, 2018 WL 3446236, at *2 (Mich. Ct. App. July 17, 2018) ("Local governments may control and regulate matters of local concern so long as their regulations do not conflict with state law.").

## III. PLAINTIFF'S MICHIGAN CONSUMER PROTECTION ACT CLAIM FAILS FOR ADDITIONAL REASONS (COUNT 3).

The Manufacturer Defendants' alleged conduct falls under the MCPA's safe harbor. Although Plaintiff *concedes* that "regulated activity" is immune under the MCPA "even if, under the regulation, the legality of [the conduct] is in dispute," Opp. 26 & n.24, Plaintiff nevertheless asserts that "the deceptive unbranded marketing campaign, deceptive off-label marketing, and the failure to disclose their falsity" are outside the scope of that regulated activity, *id.* at 27. This argument flatly contradicts the 2AC, which expressly alleges that FDA engaged in various regulatory and enforcement actions against the Manufacturer Defendants for *precisely* this kind of conduct. *See*, *e.g.*, 2AC ¶¶ 702-08. Not surprisingly, Michigan courts recognize that when FDA has approved a product, the MCPA does not apply. *See*, *e.g.*, *Peter v. Stryker Orthopaedics, Inc.*, 581 F. Supp. 2d 813, 816 (E.D. Mich. 2008).[5]

Even setting aside the safe harbor, the Manufacturer Defendants' alleged acts are not "in the conduct of trade or commerce" as required under the MCPA. "[T]he MCPA applies only to purchases *by consumers*," *Slobin v. Henry Ford Health Care*, 666 N.W.2d 632, 634 (Mich. 2003)—and Plaintiff *concedes* it is not a consumer, Opp. 36. That concession is fatal.

## IV. PLAINTIFF'S PUBLIC NUISANCE CLAIM FAILS FOR ADDITIONAL REASONS (COUNT 4).

The Opposition fails to identify a "public right" sufficient to allege a public nuisance. Instead, Plaintiff conflates the distinct concepts of a "public right" and an "unreasonable interference," Opp. 19, and mistakes "the number of people affected" for the *nature* of the right impli-

[5] Plaintiff claims, with no support, that "the issue of whether the conduct at issue in the MCPA claims is subject to a specific regulation is one of fact" or, alternatively, "an affirmative defense," and so should not be decided at the motion-to-dismiss stage. Opp. 28-29. But Plaintiff concedes that dismissal is appropriate even for affirmative defenses if "the plaintiff's own allegations show that a defense exists that legally defeats the claim." *Id.* at 28 (quoting *Marsh v. Genentech, Inc.*, 693 F.3d 546, 554-55 (6th Cir. 2012)). Nor is there any factual question to decide; assuming all the allegations in the 2AC are true, whether the alleged conduct is within FDA and DEA's regulatory authority is a *question of law*.

cated, *id.* at 20. *See Summit* Reply 27-28 & n.23.[6] Even assuming that Plaintiff could establish the existence of a public right, the Manufacturer Defendants' conduct was authorized by law and therefore cannot constitute an "unreasonable interference" with that right. Plaintiff's lone argument to the contrary rests on the erroneous contention that the Manufacturer Defendants had an obligation to monitor *downstream* sales for suspicious orders. *Summit* JM 32. And Plaintiff's allegations of misleading promotion not only lack the requisite particularity, *id.* 33-34, but implicate an individual, as opposed to public, right not to be defrauded. *Summit* Reply 27-28.

Finally, Plaintiff does not dispute that the chain of causation between the alleged conduct and public nuisance has many links, including criminal acts by third parties, over which the Manufacturer Defendants lack control. Instead, Plaintiff argues those third-party acts do not break the causal chain because of decisions—*City of Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136 (Ohio 2002), and *James v. Arms Tech. Inc.*, 820 A.2d 27 (N.J. 2003)—that allowed claims to proceed where the defendants controlled their *own* conduct. Opp. 22-23. Plaintiff ignores the more relevant authorities holding that there can be no public nuisance liability where, as Plaintiff concedes here, defendants lacked control over third-party criminal actors. *Camden Cty. Bd. of Chosen Freeholders v. Beretta U.S.A. Corp.*, 273 F.3d 536, 539, 541 (3d Cir. 2001); *Dist. of Columbia v. Beretta U.S.A. Corp.*, 872 A.2d 633, 646-51 (D.C. App. 2005); *City of Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099, 1136-38 (Ill. 2004); *People ex rel. Spitzer v. Sturm, Ruger & Co.*, 309 A.D.2d 91, 104-05 (N.Y. App. Div. 2003). Under these authorities, there is no nuisance where, as here, the defendant provides a lawful and highly regulated product, and the alleged nuisance arises after many steps removed from a manufacturer's initial sale.

[6] Plaintiff's sole case on this point, *Mayor of Detroit v. Arms Tech., Inc.*, 669 N.W.2d 845 (Mich. Ct. App. 2003), is wholly inapposite. Dismissing on state-level preemption grounds a city's public nuisance claim against gun manufacturers, distributors, and retailers, the appellate court merely noted that the trial court "rejected the defendants' argument that public nuisance relates to the use of land," *id.* at 854, which is an argument neither urged here nor considered there.

*Chicago*, 821 N.E.2d at 1136-38.[7]

## V. PLAINTIFF'S NEGLIGENCE CLAIM FAILS FOR ADDITIONAL REASONS (COUNT 5).

In addition to its failure to plead causation and an actionable injury, Plaintiff has not adequately pleaded that the Manufacturer Defendants owe a duty of care to Plaintiff. Plaintiff relies on the purported foreseeability of its alleged injuries to establish the existence of such a duty, Opp. 44, but Michigan law does not impose "a duty to protect everybody from all foreseeable harms." *In re Certified Question from Fourteenth Dist. Ct. of App. of Tex.*, 740 N.W.2d 206, 212 (Mich. 2007). Rather, Michigan courts have refused to impose a duty when, as here, the relationship between the parties is "highly tenuous." *Id.* at 216, 222; *see also Bank of Am. Corp. v. City of Miami*, 137 S. Ct. 1296 (2017) (proximate cause requires a "direct relation between the injury asserted and the injurious conduct alleged").[8]

## VI. PLAINTIFF'S UNJUST ENRICHMENT CLAIM FAILS FOR ADDITIONAL REASONS (COUNT 6).

Under Michigan law, only those who entered into *direct* transactions with the defendant can bring unjust enrichment claims. JM 17-18. Plaintiff wrongly claims that equity absolves it of the direct transaction requirement. Opp. 50. But the cases Plaintiff cites are inapposite or support dismissal, as they either did not analyze unjust enrichment as a standalone claim, did not substantively analyze the direct benefit requirement, or, unlike here, involved a direct relationship

[7] Moreover, the municipal-cost-recovery rule would likely preclude recovery. JM 16-17. In response, Plaintiff cites *Archer v. Arms Tech., Inc.*, 2000 WL 35624356, slip op. at 7 (Mich. Cir. Ct. May 16, 2000), as authority that Michigan does not recognize the doctrine. *See* Opp. 16; Opp. Ex. 1 (Dkt. #729-1). But *Archer* actually held the opposite: the municipal-cost recovery rule *does* apply, with narrow exceptions where recovery is "authorized by statute or regulation," where "the government incurs expenses to protect its own property," and where recovery is "required to effect the intent of federal legislation." Opp. Ex. 1, at 14. None of those exceptions applies here.

[8] Plaintiff's reliance on *Cleveland Indians Baseball Co., L.P. v. New Hampshire Ins. Co.*, for such a duty is misplaced, Opp. 43, as the Manufacturer Defendants and Plaintiff are not "contracting part[ies]," *see* 727 F.3d 633, 638-39 (6th Cir. 2013) (with respect to providers of professional services, "*a contracting party* owes a separate and distinct common law duty of care . . .").

between the parties.[9]

## VII. PLAINTIFF'S FRAUD CLAIM FAILS FOR ADDITIONAL REASONS (COUNT 7).

Plaintiff concedes that an indirect fraud claim based on a third-party misrepresentation requires "'intent and expectation that the misrepresentation would be repeated to induce reliance by a principal participant to a business undertaking.'" Opp. 60 (quoting *Nernberg v. Pearce*, 35 F.3d 247, 251 (6th Cir. 1994)). Yet nowhere does the 2AC allege that Manufacturer Defendants made statements to physicians intending that they would be repeated *to Monroe County*, which would then rely on them. Nor is Plaintiff a principal participant to any business undertaking with any Manufacturer Defendant. Moreover, Plaintiff has no answer to the fact that the Manufacturer Defendants expressly disclosed all relevant risks in FDA-approved labels, which physicians are required to review. JM 18-19. Indeed, Plaintiff does not even address the Michigan precedent holding that such labeling successfully communicates the risks at issue in the purported misrepresentations. *Id.*

## CONCLUSION

The Court should dismiss the 2AC with prejudice.

Dated: July 30, 2018

Respectfully submitted,

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[9] For instance, the parties had a direct financial relationship in *Tkachick v. Mandeville*, 790 N.W.2d 260, 266-268, 271 (Mich. 2010). Moreover, *Kammer Asphalt Paving Co. v. E. China Twp. Sch.*, 504 N.W.2d 635, 640-41 (Mich. 1993), is distinguishable because the defendant directly assured the plaintiff of payment—unlike here, where Plaintiff alleges that Manufacturer Defendants misled third parties (i.e., physicians) and alleges no communications with Plaintiff.

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**LOCAL RULE 7.1(F) CERTIFICATION**

I certify that this case has been assigned to the "litigation track" pursuant to CMO One and that this Memorandum adheres to the page limitations set forth in CMO Four at 3.

Dated: July 30, 2018

/s/ Brien T. O'Connor
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**CERTIFICATE OF SERVICE**

I hereby certify that on July 30, 2018, a copy of the foregoing **Reply in Support of the Manufacturer Defendants' Joint Motion to Dismiss Plaintiff's Second Amended Complaint** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

Dated: July 30, 2018

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